

FDA Regulation of Personal Protection Equipment (PPE) for Healthcare workers

Miriam C. Provost, Ph.D.

Deputy Director, Office of Device Evaluation

Center for Devices and Radiological Health

Food and Drug Administration

What is a Medical Device?

- **An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or similar article.**
 - **Intended for use in the diagnosis of disease or other condition or in the cure, mitigation, treatment, or prevention of disease in man,**
- OR**
- **Intended to affect the structure or any function of the body of man**
- AND**
- **does not achieve its primary purpose through chemical action within or on the body of man and which is not dependent upon being metabolized for the achievement of its primary intended purposes.**

Medical Device Regulation is a risk-based classification process

- **Three classes: I, II and III**
- **Hierarchy of controls, both pre- and post-market**
- **Regulations are written with the idea that devices are to regulated at the lowest possible level**

510(k) submissions

- **A marketing application for a Class I or Class II device (a.k.a., Premarket Notification Submission)**
- **A 510(k) is required when introducing a Class II (or sometimes Class I) device to the market for the first time, making a change in the intended use and/or making a “significant” change to the device design**
- **FDA receives approximately 4500 510(k) applications per year (Number begins with “K”)**
- **A 510(k) device if it is substantially equivalent (SE) to a legally marketed device:**
 - **same intended use and**
 - **similar technological characteristics**
 - **OR different technological characteristics but no new types of safety or effectiveness concerns.**

510(k) submissions

- **Performance testing (bench \pm animal) is often required and is usually sufficient to answer questions and get clearance.**
- **Clinical data may be required depending on differences with predicate device.**
- **Review time - 90 days (total FDA time)**
- **No pre-approval inspection of manufacturing facilities**
- **No annual reporting requirements (besides Medical Device Reporting)**

Determining whether a device is substantially equivalent

- **Analyses and testing must compare the proposed device to the predicate device**
- **Testing must show that new device does not raise a “new type” of safety and effectiveness**
- **Consider both technology AND proposed intended use/indication for use**

Postmarket Controls

- **Registration and Listing**
- **Quality System Regulation (21 CFR 820)**
 - Periodic inspection
 - Enforcement actions: warning letters, injunction, seizure, civil money penalties
- **Medical Device Reporting**
 - Manufacturers & importers of medical devices must report **device related deaths, serious injuries, and malfunctions** to FDA within 30 days. (5 days if remedial action to prevent an unreasonable risk of substantial harm to the public health.)
 - User facilities must report **suspected medical device related deaths** or **serious injuries** to the FDA and manufacturer within 10 days.

Personal Protective Equipment Regulated by FDA

21 CFR 878.4040 Surgical Apparel

- **Devices intended to be worn by operating room personnel during surgical procedures to protect both the patient and the operating room personnel from the transfer of microorganisms, body fluids and particulate materials**
- **Includes Surgical Masks and Surgical N95 Respirators , Surgical Gowns and Isolation Gowns, Goggles and Face Shields, Surgical Caps, Hoods, Shoe Covers and Boots**
- **Class II for surgical gowns and surgical masks/respirators, requires 510(k), subject to QSR**
- **Class I for others, exempt from 510(k), subject to QSR**

Personal Protective Equipment Regulated by FDA

21 CFR 878.4460 Surgeon's Glove

- A device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.
- Class I, requires submission of 510(k)
- Must be manufactured under the Quality System Regulation

Personal Protective Equipment Regulated by FDA

21 CFR 880.6250 Patient Examination Glove

- A disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner
- Class I, requires 510(k)
- Must be manufactured under the Quality System Regulation

Relevant FDA Guidance Documents

- **Guidance for Industry and FDA - Medical Glove Guidance Manual,**
<http://www.fda.gov/cdrh/dsma/135.html>
- **Surgical Masks - Premarket Notification [510(k)] Submissions; Guidance for Industry and FDA**
- <http://www.fda.gov/cdrh/ode/guidance/094.html>
- **Guidance on Premarket Notification [510(k)] Submissions for Surgical Gowns and Surgical Drapes**
- <http://www.fda.gov/cdrh/ode/888.pdf>

Contact Information

Miriam Provost, Ph.D.
Deputy Director
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
(240) 276-3993

Miriam.provost@fda.hhs.gov

